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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/942,941 | 08/31/2001 | Shirley I. Miekka | CI-003 | 8965 |

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MORGAN LEWIS & BOCKIUS LLP
1111 PENNSYLVANIA AVENUE NW
WASHINGTON, DC 20004

| EXAMINER | |
|---|---|
| SMITH, JOHNNIE L | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 2881 | |

DATE MAILED: 07/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/942,941 | MIEKKA ET AL. | |
| | Examiner | Art Unit | |
| | Johnnie L. Smith II | 2881 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *98-135* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *98-135* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 98-135 are rejected under 35 U.S.C. 103(a) as being obvious over US 6,696,060 (Grieb et al).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be

overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

4. In reference to claims 98-100 and 133-135, Grieb et al teach a method for sterilizing a preparation of immunoglobulin that is sensitive to gamma radiation comprising irradiating said preparation with gamma radiation at a rate of greater than 3.0 kGy/hr for a time effective to inactivate at least one biological contaminant or pathogen in said preparation (Claim 1, column 17 line 58- column 18 line 55). Grieb et al teach all aspects of the said claims, but fail to clearly discuss the method sterilizing pathogen in a preparation containing albumin; in a

plasma protein fraction preparation; or in a plasma protein fraction preparation as being claimed by applicant. It would have been obvious to one of ordinary skill in the art at the time of the invention to sterilize the specific preparations being claimed since Grieb does teach the sterilization of blood components and the said preparations are considered art equivalents.

5. In reference to claim 101, Grieb et al teach a method further comprising reducing residual solvent present in said preparation to a level effective to protect said preparation from said gamma radiation (claim 1). In reference to claim 102, Grieb et al teach a method further comprising adding to said preparation at least one stabilizer in an amount effective to protect said preparation from said gamma radiation (claim 2). In reference to claim 103, Grieb et al teach a method further comprising reducing the temperature of said preparation to a level effective to protect said preparation from said gamma radiation (column 14 lines 11-24).

6. In reference to claim 104, Grieb et al teach a method further comprising at least two of; reducing residual solvent present in said preparation to a level effective to protect said preparation from said gamma radiation (claim 1); adding to said preparation at least one stabilizer in an amount effective to protect said preparation from said gamma radiation (claim 2), and reducing the temperature of

said preparation to a level effective to protect said preparation from said gamma radiation (column 14 lines 11-24).

7. In reference to claim 105, Grieb et al teach a method for use with albumin 9column 17 line 58- column 18 line 55). In reference to claims 106-108, Grieb et al teach a method for use with various proteins (column 1 lines 14-29). In reference to claims 109-111, Grieb et al teach a method wherein said rate is greater than about 6.0kGy/hr (claim 47), greater than about 18kGy/hr (claim 48), and greater than about 30.0kG/hr (claim 49).

8. In reference to claim 112, Grieb et al teach a method wherein said residual solvent is water (claims 7-10). In reference to claim 113, Grieb et al teach a method wherein said residual solvent is an organic solvent (claims 11-18). In reference to claim 114, Grieb et al teach a method wherein said residual solvent is reduced by a method selected from the group consisting of lyophilization, concentration, addition of solute, chemical extraction, spray-drying and vitrification (claim 53).

9. In reference to claims 115 and 116, Grieb et al teach a method wherein the content of said residual solvent present in said preparation after said reduction is less than about 10% (claim 54) or is less than about 5% (claim 55). In reference to claims 117-119, Grieb et al teach a method wherein said at least one stabilizer is an

antioxidant (claim 63), is a free radical Scavenger (claim 64), or is selected from the group consisting of ascorbic acid or a salt or an ester thereof (claim 66).

10. In reference to claims 120-125, Grieb et al teach a method wherein said temperature is reduced below ambient temperature (claim 71), is reduced below the freezing point of said preparation (claim 73), is reduced below the eutectic point of said preparation (claim 74), is reduced below 0 degrees, minus 40 degrees, or minus 60 degrees (column 14 lines 11-24). In reference to claim 126, Grieb et al teach a method wherein said gamma irradiation is administered for a time effective to sterilize said preparation (read in claim 1).

11. In reference to claims 127-129, Grieb et al teach all elements of the base claims including limitations of albumin irradiation, but failed to clearly discuss applicants specific groups being claimed herein. It would be obvious to one of ordinary skill in the art at the time of the invention to have such preparations since the said preparation are well known in that art for use with blood components, and one would be compelled to do so because the said preparations are common medias upon which various materials are prepared.

12. In reference to claim 130-132, claims 1-78 in combiantnation read on claims 130-132, since the said claims are product of the process being claimed by Grieb.

*Conclusion*

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. All of the cited references cited on attached PTO 892, contain art similar to that being claimed by applicant, more specifically, methods and apparatus for radiation sterilization of biologically active compounds.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Johnnie L. Smith II whose telephone number is

571-272-2481. The examiner can normally be reached on Monday-Thursday 7-4 P.M. and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John R. Lee can be reached on 571-272-2477. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Johnnie L Smith II
Examiner
Art Unit 2881

JLSII

JOHN R. LEE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800